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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/932,935 09/18/97 WOHLSTADTER

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<input type="checkbox"/>	<input type="checkbox"/>	EXAMINER
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HM12/0824

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ART UNIT

PAPER NUMBER

1641

17

DATE MAILED:

08/24/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No. 08/932,985	Applicant(s) Wohlstadter et al
Examiner Chris Chin	Art Unit 1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on Jun 11, 2001.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) Claim(s) 5-12, 33-36, and 46-93 is/are pending in the application.

4a) Of the above, claim(s) 33-36, 63-68, and 87-90 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 5-12, 46, 52, 54-62, 69-71, 73, 76-79, 83-86, and 91-93 is/are rejected.

7) Claim(s) 47-51, 53, 72, 74, 75, and 80-82 is/are objected to.

8) Claims 5-12, 33-36, and 46-93 are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are objected to by the Examiner.

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) All b) Some* c) None of:

- Certified copies of the priority documents have been received.
- Certified copies of the priority documents have been received in Application No. _____.
- Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) Notice of References Cited (PTO-892)

16) Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) Information Disclosure Statement(s) (PTO-1449) Paper No(s). 16

18) Interview Summary (PTO-413) Paper No(s). _____

19) Notice of Informal Patent Application (PTO-152)

20) Other: _____

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DETAILED ACTION

Election/Restriction

1. Newly submitted claims 87-90 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

New claim 87 is directed to a separate and patentably distinct apparatus because it contains a cartridge and cartridge receptacle that is not part of the elected and previously examined apparatus.

New claims 88-90 are directed to methods for conducting an electrochemiluminescence binding assay. These methods are patentably distinct from the elected and previously examined apparatus because the elected apparatus can be used in a materially different process such as mixing PCR solutions or other reagents.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 87-90 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

2. This application contains claims 33-36, 63-68 and 87-90 drawn to an invention nonelected with traverse in Paper No. 15. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

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Claim Rejections - 35 U.S.C. § 112

3. Claims 8, 9, 54-62, 70, 73, 76-79, 84, 86, and 92 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 8 and 72 are vague and indefinite. In line 4, the recitation of “adapted for” is not clear as to how the counter electrode is modified to conduct the electrochemiluminescence assay.

Claim 9 is vague and indefinite. The recitation of “adapted for” in part (a) is not clear as to how the cell has been modified to conduct the assays. The recitation of “adapted to” in part (b) is not clear as to how the sonication device has been modified to increase the rate of the binding reaction within the cell.

Claim 70 is vague and indefinite. The recitation of “adapted for” in part © is not clear as to how the light detector is modified to detect or measure luminescence.

Claims 76 and 77 are vague and indefinite. The recitation of “adapted for” in line 2 of each claim is not clear as to how the sonication device is modified to increase the rate of fluid flow.

Claims 78 and 79 are vague and indefinite. The recitation of ‘adapted to” in line 2 of each claim is not clear as to how the means is modified to increase the rate of fluid flow. Also, with respect to claim 79, claim 70 (from which claim 79 depends from) fails to recite a “means” so the recitation of “said means” lacks antecedent support.

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Claim Rejections - 35 U.S.C. § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371C of this title before the invention thereof by the applicant for patent.

5. Claims 5, 9, 12, 46, 52, 55, 61, 69, 70, 73, 83, 84, 85, 86, and 91-93 are rejected under 35 U.S.C. 102(b) as being anticipated by Northrup et al.

Northrup et al (U.S. Patent 5,674,742) discloses an instrument for performing PCR-based diagnostics. The components of the instrument include reservoirs for retaining reagents, agitators and mixers, heaters to perform denaturing and annealing cycles, pumps, optical and/or electromechanical sensors to discriminate reagents and reagent separators (col. 4, lines 60-68, and col. 5, lines 1-20). Figure 2 shows an embodiment of the disclosed instrument which comprises three reagent chambers (10), (12), and (14). Chamber (10) contains the DNA primers, chamber (12) contains the polymerase, and chamber (14) contains the nucleotides and any detection-tag molecules, such as magnetic beads (i.e. one or more solid supports having one or more binding domains formed thereon). The reactants in reagent chambers (10), (12), and (14) are connected by channels (22), (24), and (26) to a reaction chamber (30) (i.e. a cell). Reaction chamber (30) is

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equipped with a Lamb-wave transducer (i.e. a sonication device) and a heater. The Lamb-wave transducer acts as an agitator, mixer, or sonochemical inducer. A channel (32) connects the reaction chamber (30) to a detection chamber (34). The detection chamber (34) may be provided with an optical window and testing may be performed by fluorescence-based or absorption-based optical spectroscopy (col. 7, lines 9-68, and col. 8, lines 1-44).

6. Claims 9, 10, 12, 52, and 61 are rejected under 35 U.S.C. 102(b) as being anticipated by Grant et al for the reasons of record in paper 12.

In response to this rejection, Applicants argue that the system disclosed in Grant et al does not have binding domains or binding reagents.

Applicant's arguments have been considered but are not convincing. Claim 9 recites an apparatus for use in conducting a binding assay. However, claim 9 fails to recite any positive limitations setting forth reagents for carrying out the binding assay. Part (a) of claim 9 stipulates that the cell is "adapted for conducting assays which involve binding reagents" but this recitation is not a positive limitation saying that binding reagents are actually part of the cell. Part (b) of claim 9 stipulates that the sonication device is "for sonicating said binding assay reagents" but this recitation is not a positive limitation saying that binding reagents are actually present. Essentially, claim 9 recites an apparatus comprising a cell and a sonication device in solid contact with the cell. The system of Grant et al meets the limitations of claim 9 and the claims listed in the rejection that depend from claim 9.

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7. Claim 9 is rejected under 35 U.S.C. 102(b) as being anticipated by Walter for the reasons of record in paper 12.

In response to this rejection, Applicants argue that Walter fails to disclose a cell having binding domains or binding reagents.

Applicant's arguments have been considered but are not convincing. Claim 9 recites an apparatus for use in conducting a binding assay. However, claim 9 fails to recite any positive limitations setting forth reagents for carrying out the binding assay. Part (a) of claim 9 stipulates that the cell is "adapted for conducting assays which involve binding reagents" but this recitation is not a positive limitation saying that binding reagents are actually part of the cell. Part (b) of claim 9 stipulates that the sonication device is "for sonicating said binding assay reagents" but this recitation is not a positive limitation saying that binding reagents are actually present. Essentially, claim 9 recites an apparatus comprising a cell and a sonication device in solid contact with the cell. The system of Walter meets the limitations of claim 9 and the claims listed in the rejection that depend from claim 9.

Claim Rejections - 35 U.S.C. § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 6, 7, 10, 11, and 71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Northrup et al.

See above for the teachings of Northrup et al.

Northrup et al differs from the instant invention in failing to teach the Lamb-wave transducer (sonication device) generates a specific range of sonication energy of 0.1 to 10,000 kHz and power of 0.001 to 10 watts.

However, the optimum range of sonication energy and power can be determined by routine experimentation and thus would have been obvious to one of ordinary skill in the art.

Allowable Subject Matter

10. Claims 47-51, 53, 72, 74, 75, and 80-82 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chris Chin whose telephone number is (703) 308-3991. The examiner can normally be reached on Monday-Thursday from 9:30 am to 7:00 pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (703) 305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

cchin/cc
August 22, 2001

Christopher L. Chin
CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP 1800-1641